

## **II. REMARKS**

### **A. Status of the claims**

Claim 41 has been amended for proper antecedent basis.

New claims 56, 57 and 58 have been added. Support for these claims can be found, e.g., in paragraph [0014] and Examples 1-13 of the specification.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-58 are pending, and are encompassed by the elected invention (including the elected species).

### **B. Substance of Interview**

In accordance with the provisions of 37 CFR 1.133, Applicants herein make of record the substance of the telephonic interview conducted on April 18, 2011, between the undersigned attorney and Primary Examiner Isis A. Ghali.

During the interview, U.S. Patent No. 6,103,735 to Aslanian et al. ("the Aslanian reference") was discussed in view of "the active ingredient consisting of loratadine or a pharmaceutically acceptable salt thereof" language recited in independent claims 8, 20 and 46. It was submitted that the Aslanian reference describes, e.g., in column 1, lines 10-12, "compositions which comprise combinations of antagonists of neurokinin receptors and antagonists of histamine receptors," and therefore the Aslanian reference (alone or in combination with the Kogan reference) cannot render obvious a transdermal delivery system which does not contain a neurokinin receptor antagonist.

The Examiner indicated that the term “comprising” in the preamble of claims 8, 20 and 46 does not preclude the possibility of other active agents being present in the claimed transdermal delivery systems, and that, in her opinion, a further amendment specifying that loratadine is the only active agent in the presently claimed transdermal delivery systems is unlikely to advance prosecution of the present application, because the Kogan reference describes transdermal compositions containing loratadine and no additional active agents.

As explained below, the Examiner’s position regarding the further amendment is incorrect, because the rejection is over the **combination** of the Kogan reference with the Aslanian reference (rather than the Kogan reference alone), and the combination of the cited references suggests a transdermal delivery system comprising both a neurokinin receptor antagonist and a histamine receptor antagonist(s) (e.g., loratadine). Moreover, as explained below, the inventive composition of the Aslanian reference and the purportedly intended purpose of the Aslanian reference (enhancement of efficacy of neurokinin antagonists) would be destroyed by removal of the neurokinin receptor antagonists from the transdermal delivery systems suggested by the combination of the cited references. For these reasons, the combination of the cited references cannot render obvious a transdermal delivery system wherein the only active agent in the transdermal delivery system is loratadine.

Applicants thank the examiner for participating in the interview, and respectfully request that this Substance of Interview be made of record.

**C. Rejections under 35 U.S.C. § 103**

**1. The Kogan reference in view of the Aslanian reference**

Claims 8-11, 13, 14, 16, 20-23, 29, 30, 32, 40-42, 45-49, and 53-55 have been rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,910,205 to Kogan et al. (“the Kogan reference”) in view of the Aslanian reference.

The rejection is respectfully traversed.

Applicants respectfully submit that the present rejection cannot be maintained and should be withdrawn because (i) the combination of the cited references on its face does not teach or suggest all the elements of the present claims, (ii) the rejection impermissibly imports elements from the specification into the present claims, (iii) Applicants have established that the elements of the present claims are not taught or suggested by the combination of the cited references, and (iv) a *prima facie* case of obviousness cannot be established by using the combination of the cited references.

a) **The combination of the cited references on its face does not teach or suggest all the elements of the present claims**

This is a new rejection in the present application. All of the previous rejections were withdrawn in response to the Appeal Brief filed on November 17, 2010. This is the second time the prosecution of the present application is being reopened in response to the filed Appeal Brief<sup>1</sup>, with all of the rejection of record withdrawn and new rejections interposed.

For over seven years, the Examiner repeatedly stated that the Kogan reference “does not teach the specific delivery profile of loratadine ....” See, e.g., Office Action mailed on January 5, 2010, page 5. The Examiner now purports that this deficiency is cured by the Aslanian reference, which was brought to the Examiner’s attention in an Information Disclosure Statement filed on June 13, 2003, but is only now being cited by the Examiner in an obviousness rejection.

Applicants respectfully submit that the Aslanian reference cannot cure this deficiency of the Kogan reference as articulated by the Examiner, because the Aslanian reference does not teach or suggest the specific delivery profile of loratadine. Applicants

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<sup>1</sup> The prosecution was previously reopened with all rejections of records withdrawn and new rejections interposed in the response to the Appeal Brief filed on April 27, 2006.

respectfully note that the only disclosure of transdermal delivery in the Aslanian reference is in column 7, lines 7-12, reciting:

The compounds of the invention may also be deliverable transdermally. The transdermal compositions may take the form of creams, lotions, aerosols and/or emulsions and can be included in a transdermal patch of the matrix or reservoir type as a re [sic] conventional in the art for this purpose.

This disclosure of the Aslanian reference clearly cannot teach or suggest the feature which according to the Examiner is missing from the Kogan reference (i.e., the specific delivery profile of loratadine), as there is no mention of the missing feature in this disclosure.

For this reason alone (the combination of the cited references on its face does not teach or suggest all the elements of the present claims), and for the additional reasons provided below, the present rejection cannot be maintained and should be withdrawn.

**b. The rejection imports elements from the specification**

Applicants respectfully submit that the rejection is improper, because it is based on the present specification and impermissibly imports elements from the present specification into the present claims.

The Manual of the Patent Examining Procedure states:

**... IT IS IMPROPER TO IMPORT CLAIM LIMITATIONS FROM THE SPECIFICATION**

‘Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.’ *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of

the patent must be construed as being limited to that embodiment); < *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) ("Interpretation of descriptive statements in a patent's written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims."); *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003) (Although the specification discussed only a single embodiment, the court held that it was improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order) ...

See, MPEP, section 2111.01 (emphasis added).

The Examiner supports the instant rejection by stating on page 10 of the Office Action that that "since the **instant specification** teaches the same amount of loratadine [as disclosed in the Aslanian reference] ..." it is expected that the claimed properties will flow from the combined teachings of the references. (emphasis added). The Examiner further states that "[i]n present example 8 [sic] applicants use 0.12 gm loratadine, i.e., 120 mg." Office Action, page 9. The Examiner concludes that "[t]herefore, in the light of Aslanian teaching, at the time of the invention it was known to load 120 mg of loratadine in a single dosage form as a therapeutically effective dose of loratadine for treating allergic rhinitis." Id.

Applicants respectfully submit that the present specification, including Example 8, is not "prior art" and therefore cannot be used to support the present rejection.

Applicants further submit that the present claims do not recite any loratadine amounts, and therefore, the Examiner's reliance on the 120 mg of loratadine disclosed in Example 8 impermissibly imports limitations from the present specification into the present claims.

Moreover, Applicants submit that the purported disclosure of “1-200 mg of H1 antagonist” in the Aslanian reference is not relevant to the present claims, because the present claims do not recite any amounts of loratadine.

For these reasons (the reliance on the specification and the importation of claim limitations from the specification), the rejection should be withdrawn. See, e.g., MPEP, section 2111.01 (“IT IS IMPROPER TO IMPORT CLAIM LIMITATIONS FROM THE SPECIFICATION”).

**c. The elements of the present claims are not taught or suggested by the combination of the cited references**

Independent claims 8, 20 and 46 all recite that the transdermal delivery system maintains “a steady state plasma concentration of loratadine of about 3 ng/ml” and specific delivery profiles of loratadine.

Applicants respectfully submit that the steady state plasma concentration of loratadine and the specific delivery profiles of loratadine (mean delivery rates at 24 hours, 48 hours, 72 hours and 96 hours) recited in present independent claims 8, 20 and 46 are not taught or suggested by the combination of the cited references.

The Examiner acknowledged on page 8 of the Office Action that “Kogan does not explicitly teach the same plasma level of loratadine as instantly claimed.” The Examiner however took the position that “the plasma level of loratadine displayed by the Kogan would be the same as claimed.”

Applicants submit that as demonstrated in the Appeal Brief filed on November 17, 2010, the steady state plasma concentration of loratadine purportedly suggested by the Kogan reference is different from the steady state concentration of loratadine recited in instant independent claims 8, 20 and 46.

The steady state plasma concentration of loratadine purportedly suggested by the Kogan reference can be calculated by using the information provided in the present specification. The present specification describes two formulas for calculating the dosing rate of loratadine (i.e., the amount of drug released per unit time from transdermal delivery system through the skin and into the bloodstream of a human patient). See paragraph [0123].

First, the specification states that the dosing rate is “a product of the steady state concentration of loratadine and a representative clearance rate.” See paragraph [0123]. In other words, according to the present specification, dosing rate =  $C_{ss} \times CL$ , where  $C_{ss}$  is loratadine’s steady-state concentration, and CL is loratadine’s clearance rate. The steady-state concentration of loratadine may therefore be calculated by dividing the dosing rate of loratadine by its clearance rate. In other words,  $C_{ss} = \text{dosing rate} / CL$ .

The “flux” of the Final Gel of Table I of the Kogan reference (the highest flux listed in Table I) is “2.26 mg/15 cm<sup>2</sup>/day,” or 94167 ng/hour ( $2.26/24 \times 1000000 = 94167$ ). The clearance rate of loratadine is 196000 ml/hr. See paragraph [0123]. The calculated steady state loratadine concentration after administration of the Final Gel of Kogan at approximately steady state is therefore 0.48 ng/ml ( $94167/196000 = 0.48$ ). This calculated steady state concentration does not overlap with the steady state concentration of “about 3 ng/ml” recited in instant claim 8.

Similarly, calculating loratadine’s steady state concentration after administration of the Final Gel of the Kogan reference by using the second formula described in the present specification does not overlap with the steady state concentration of “about 3 ng/ml” recited in the present claims. The present specification states that the dosing rate is equal to the “[t]he product of steady state concentration, volume of distribution and elimination rate constant.” See paragraph [0123]. The elimination rate constant is “0.693/half-life.” See Id. In other words, the dosing rate =  $C_{ss} \times V_d \times 0.693/\text{half-life}$ , where  $C_{ss}$  is loratadine’s steady state plasma concentration and  $V_d$  is its volume of distribution. The steady-state concentration of loratadine may be calculated by dividing

the dosing rate by loratadine's volume of distribution and elimination rate constant. In other words,  $C_{ss} = \text{dosing rate} / (V_d \times 0.693 / \text{half-life})$ .

The dosing rate at approximate steady state after administration of the Final Gel of the Kogan reference is 2.26 mg/15cm<sup>2</sup>/day, or 94167 ng/hour (2.26/24x1000000=94167). See Table I of the Kogan reference. According to the present specification, loratadine's  $V_d$  is 1660000 ml, and loratadine's half-life is 8.4 hours. See paragraph [0123]. The calculated steady state loratadine concentration after administration of the Final Gel at approximately steady state of the Kogan reference is therefore 0.69 ng/ml (94167/(1660000x0.693/8.4))=0.69).

This calculated steady state concentration of loratadine is in sharp contrast to the steady state concentration of "about 3 ng/ml" recited in independent claims 8, 20 and 46. Specifically, the steady state concentration of loratadine recited in the present claims is 4.3 times higher or 6.3 times higher than the 0.69 ng/ml and 0.48 ng/ml steady state loratadine concentrations calculated from the flux data of the Kogan reference.

Applicants respectfully submit that the skilled person would understand that "about 3 ng/ml" does not encompass values that are 4.3 times lower or 6.3 times lower than 3 ng/ml.

Accordingly, Applicants submit that "a plasma level of loratadine at steady state of about 3 ng/ml" is not expected from the devices and cannot be inherent in the cited references.

Applicants respectfully reiterate that it has been held that references which do not teach the specific pharmacokinetic parameters do not render these pharmacokinetic parameters obvious. Specifically, the court stated that "just as the absence of the PK [pharmacokinetic] limitations ... was sufficient ... to defeat an anticipation claim; **it is also sufficient here to defeat ... [an] obviousness challenge**". See *Abbott Laboratories v. Sandoz, Inc.*, 2007 WL 4287501 at 28 (N.D.Ill 2007) (emphasis added).

Accordingly, the combination of the cited references does not and cannot teach a transdermal delivery system providing the claimed steady state plasma level of loratadine and the claimed release profile of loratadine (specific mean delivery rates at 24, 48, 72 and 96 hours) as recited in claims 8, 20 and 46.

Accordingly, the combination of the cited references cannot render claims 8, 20 and 46, as well as their dependent claims, obvious.

**d. A *prima facie* case of obviousness cannot be established by using the combination of the cited references**

Applicants further submit that because the combination of the cited references does not teach or suggest the plasma level of loratadine at steady state recited in the present claims, the combination of the cited references cannot teach or suggest a connection between the claimed plasma level of loratadine as steady state and the claimed mean relative release rates. Because the connection between the claimed plasma level of loratadine as steady state and the claimed mean relative release rates is not taught or suggested by the cited references, a *prima facie* case of obviousness of present independent claims 8, 20 and 46 cannot be established by using the combination of the cited references.

With further regard to claim 9, Applicants respectfully submit that the combination of the cited references does not teach or suggest a step of administering loratadine transdermally such that “the plasma level of loratadine at 48 hours does not decrease by more than 30% over the next 72 hours release” as recited in claim 9. In fact, the Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 9 has not been established.

With further regard to claim 10, Applicants respectfully submit that the combination of the cited references does not teach or suggest a step of “maintaining an effective mean relative release rate of said transdermal delivery system to provide a

substantially first order plasma level increase of loratadine from the initiation of the dosing interval until about 48 to about 72 hours after the initiation of the dosing interval; and thereafter providing an effective mean relative release rate to provide a substantially zero order plasma level fluctuation of loratadine until the end of at least the five-day dosing interval” as recited in claim 10. In fact, the Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 10 has not been established.

With further regard to claim 11, Applicants respectfully submit that the combination of the cited references does not teach or suggest a step of “maintaining an effective mean relative release rate of said transdermal delivery system to provide a substantially first order plasma level increase of loratadine from the initiation of the dosing interval until about 48 to about 72 hours after the initiation of the dosing interval; and thereafter providing an effective mean relative release rate to provide a substantially zero order plasma level fluctuation of loratadine until the end of at least the five-day dosing interval” as recited in claim 11. In fact, the Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 11 has not been established.

With further regard to claim 13, Applicants respectfully submit that the combination of the cited references does not teach or suggest a step of maintaining a plasma level of loratadine “from about 0.1 ng/ml to about 3.3 ng/ml during the dosing interval” of transdermal delivery system as recited in claim 13. In fact, the Examiner has not pointed out the portions of the cited references which describe such a step, nor were the Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 13 has not been established.

With further regard to claim 29, Applicants respectfully submit that the combination of the cited references does not teach or suggest a plasma level of loratadine “from about 0.1 ng/ml to about 3.3 ng/ml during the dosing interval” of the transdermal

delivery system” as recited in claim 29. In fact, the Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 29 has not been established.

With further regard to claim 53, Applicants respectfully submit that the combination of the cited references does not teach or suggest a method of effectively treating seasonal allergic rhinitis, chronic idiopathic urticaria, or both conditions in a human patient, transdermally, wherein the transdermal delivery system comprises “a solution of an active agent consisting of loratadine” as recited in claim 53. In fact, the Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 53 has not been established.

With further regard to claim 54, Applicants respectfully submit that the combination of the cited references does not teach or suggest a transdermal delivery system comprising “a solution of an active agent consisting of loratadine” as recited in claim 54. The Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants thus submit that a *prima facie* case of obviousness of claim 54 has not been established.

With further regard to claim 55, Applicants respectfully submit that the combination of the cited references does not teach or suggest a method of effectively treating seasonal allergic rhinitis, chronic idiopathic urticaria, or both conditions in a human patient, transdermally, wherein the transdermal delivery system comprises “a solution of an active agent consisting of loratadine” as recited in claim 55. The Examiner has not pointed out the portions of the cited references which describe such a step, nor were Applicants able to find such a step in the cited references. Applicants therefore submit that a *prima facie* case of obviousness of claim 55 has not been established.

With respect to new claims 56-58, reciting that loratadine is the only active agent in the transdermal delivery system, Applicants respectfully note that the combination of the cited references does not teach or suggest a transdermal delivery system without at least one neurokinin antagonist, because the combination of the cited references purports to suggest a transdermal delivery system comprising both a neurokinin antagonist and an antagonist of a histamine receptor (e.g., loratadine).

The Aslanian reference states that “[i]t would be highly desirable to enhance the efficacy of the neurokinin antagonists to improve their overall efficacy.” Column 2, lines 4-5. The Aslanian reference “discloses compositions which comprise **combinations** of antagonists of neurokinin receptors and antagonists of histamine receptors, and methods for treating [e.g., allergic rhinitis, and other respiratory diseases] ... with such compositions.” Column 1, lines 10-14 (emphasis added). The Aslanian reference states that its “inventive composition comprises: (i) a therapeutically effective amount of at least one neurokinin antagonist; (ii) a therapeutically effective amount of at least one H3 antagonist and (iii) a therapeutically effective amount of at least one H1 antagonist.” Column 2, lines 12-17. These compositions are used, e.g., “for treating asthma and allergic conditions ....” Column 2, lines 35-41. The Aslanian reference thus suggests that histamine receptor antagonists (e.g., loratadine) purportedly enhance the efficacy of the neurokinin receptor antagonists, e.g., in treatment of allergic disorders.

Accordingly, based on the purportedly enhanced efficacy of the neurokinin receptor antagonist in combination with histamine receptor antagonists in treatment of allergic conditions and because the removal of the neurokinin receptor antagonist would destroy the inventive composition of the Aslanian reference, the transdermal delivery system for the treatment of allergic conditions suggested by the combination of the Aslanian reference and the Kogan reference would necessarily include a neurokinin receptor antagonist.

Neurokinin receptor antagonists however are excluded from the scope of present claims 56-58, because these claims recite that “loratadine is the only active agent in the transdermal delivery system.”

For this additional reason, claims 56-58 therefore cannot be rendered obvious by the combination of the cited references. Applicants respectfully remind the Examiner that “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” See MPEP, section 2143.01. As stated above, the purportedly intended purpose of the Aslanian reference is the enhancement of efficacy of neurokinin antagonists.

For these reasons, the present rejection cannot be maintained and should be withdrawn.

In the event the Examiner seeks to maintain the rejection, Applicants respectfully request that, in the interests of compact prosecution, the Examiner addresses each of the points made above (including arguments with regard to the features recited in the dependent claims) in the next Office Action, as required by the MPEP. See, e.g., MPEP, section 707.07(f) (“... [w]here the applicant traverses any rejection, the Examiner **should**, if he or she repeats the rejection, take note of the applicant’s argument and answer the substance of it ...”) (emphasis added).

In addition, Applicants respectfully request that the Examiner provides the reasons why the previous rejection argued by the Applicants in the Appeal Brief filed on November 17, 2010 was withdrawn, by **referring specifically to the pages and lines** of the Appeal Brief which formed the basis for withdrawing the rejection, as required by the MPEP. Id. (“[i]f applicant’s arguments are persuasive and upon reconsideration of the rejection, the examiner determines that the previous rejection should be withdrawn, the examiner **must** provide in the next Office communication the reasons why the previous rejection is withdrawn by referring specifically to the page[s] and line(s) of applicant’s remarks which form the basis for withdrawing the rejection.”)(emphasis added).

**2. The Kogan reference and the Aslanian reference in view of the Venkateshwaran reference**

Claims 35, 36, 43 and 44 have been rejected under 35 U.S.C. § 103(a) over the combination of the Kogan reference, the Aslanian reference and further in view of U.S. Patent No. 5,912,009 to Venkateshwaran ("the Venkateshwaran reference").

The rejection is respectfully traversed.

Claims 35, 36, 43 and 44 depend from claim 20, through claim 23.

Claim 20 is not included in the present rejection, and is not rendered obvious by the combination of the cited references for the reasons given above in the rejection over the combination of the Kogan reference and the Aslanian reference.

Accordingly, claims 35, 36, 43 and 44 are not rendered obvious by the combination of the cited references by virtue of their dependency from claim 20.

Applicants further submit that there is no mention of loratadine in the Venkateshwaran reference. The Venkateshwaran reference therefore cannot teach that the polymer and skin softeners described therein are suitable for use in the loratadine transdermal delivery system as recited in claim 20, and it would not be obvious for one having ordinary skill in the art to use these polymers and skin softeners in the transdermal delivery system as recited in claim 20, e.g., to provide "a plasma level of loratadine at steady state of about 3 ng/ml."

Reconsideration and withdrawal of the rejection is respectfully requested.

**3. The Kogan reference and the Aslanian reference in view of the Anhauser reference**

Claims 24, 33-35, 37, 38 and 43 have been rejected under 35 U.S.C. § 103(a) over the combination of the Kogan reference, the Aslanian reference and U.S. Patent No. 6,315,854 to Anhauser et al. ("the Anhauser reference").

The rejection is respectfully traversed.

Claims 24, 33-35, 37, 38 and 43 all depend from claim 20.

Claim 20 is not included in the present rejection, and is not rendered obvious by the combination of the cited references for the reasons given above in the rejection over the combination of the Kogan reference and the Aslanian reference.

Accordingly, claims 24, 33-35, 37, 38 and 43 are not rendered obvious by the combination of the cited references by virtue of their dependency from claim 20.

Applicants further submit that there is no mention of loratadine in the Anhauser reference. The Anhauser reference therefore cannot teach that the acrylic or rubber polymers, glutaric acid monomethyl ester, flexible or non-flexible backing purportedly described therein are suitable for use in the loratadine transdermal delivery system as recited in claim 20, and it would not be obvious for one having ordinary skill in the art to use these materials in the transdermal delivery system as recited in claim 20, e.g., to provide "a plasma level of loratadine at steady state of about 3 ng/ml."

Reconsideration and withdrawal of the rejection is respectfully requested.

**4. The Kogan reference and the Aslanian reference in view of the Venkateshwaran reference and the Anhauser reference**

Claims 50-52 have been rejected under 35 U.S.C. § 103(a) over the combination of the Kogan reference and the Aslanian reference in view of the Venkateshwaran reference and the Anhauser reference.

Claims 50-52 depend from claim 8, which was not included in the present rejection and is not rendered obvious by the combination of the cited references for the reasons given above in the rejection over the combination of the Kogan reference and the Aslanian reference.

Accordingly, claims 50-52 are not rendered obvious by the combination of the cited references by virtue of their dependency from claim 8.

As stated above, there is no mention of loratadine anywhere in the Venkateshwaran reference or the Anhauser reference. These references cannot therefore teach that the solvents and skin softeners described therein are suitable for use in the loratadine transdermal delivery system in a method as recited in claim 8, and it would not be obvious for one having ordinary skill in the art to use these materials in the method of claim 8, e.g., to provide "a plasma level of loratadine at steady state of about 3 ng/ml."

Reconsideration and withdrawal of the rejection is respectfully requested.

Appl. No. 10/045,607  
Response dated May 2, 2011  
Response to Office Action dated January 31, 2011

### III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully invited to contact the undersigned by telephone, if a telephone interview would advance prosecution of the present application.

Respectfully submitted,  
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